NAILAH K. BYRD
1200 Ontario
Cleveland, OH 44113

Case# CV21943002

RETURN RECEIPT REQUESTED ELECTRONICALLY

9314 8001 1300 3543 9903 35

ZIMMER, INC.
1800 WEST CENTER STREET
WARSAW IN 46581

EXHIBIT 1

SUMMONS IN A CIVIL ACTION COURT OF COMMON PLEAS, CUYAHOGA COUNTY JUSTICE CENTER
CLEVELAND, OHIO 44113

CASE NO.		SUMMONS NO.
CV21943002	D2 CM	43458450

Rule 4 (B) Ohio Rules of Civil Procedure

SUMMONS

FRANK MAKOSKI, ET AL. — PLAINTIFF
VS
ZIMMER HOLDINGS, INC., ET AL. — DEFENDANT

ZIMMER, INC.
1800 WEST CENTER STREET
WARSAW IN 46581

You have been named defendant in a sums complaint (copy attached hereto) filed in Cuyahoga County Court of Common Pleas, Cuyahoga County Justice Center, Cleveland, Ohio 44113, by the plaintiff named herein.

You are hereby summoned and required to answer the complaint within 28 days after service of this summons upon you, exclusive of the day of service.

Said answer is required to be served on Plaintiff's Attorney (Address denoted by arrow at left.)

Your answer must also be filed with the court within 3 days after service of said answer on plaintiff's attorney.

If you fail to do so, judgment by default will be rendered against you for the relief demanded in the complaint.

Said answer is required to be served on:

Plaintiff's Attorney

RICHARD L DEMSEY
U.S. BANK CENTRE

1350 EUCLID AVE. SUITE 1550
CLEVELAND, OH 44115-0000

Case has been assigned to Judge:

RICHARD A BELL
Do not contact judge. Judge's name is given for attorney's reference only.

COMMON PLEAS COURT * CUYAHOGA COUNTY, OHIO *

NAILAH K. BYRD
Clerk of the Court of Common Pleas

DATE SENT
Jan 19, 2021

By _____
Deputy

COMPLAINT FILED 01/15/2021

CMSN130

NAILAH K. BYRD
CUYAHOGA COUNTY CLERK OF COURTS
1200 Ontario Street
Cleveland, Ohio 44113

Court of Common Pleas

New Case Electronically Filed: COMPLAINT
January 15, 2021 14:12

By: RICHARD L. DEMSEY 0003518

Confirmation Nbr. 2157986

FRANK MAKOSKI, ET AL.

vs.

ZIMMER HOLDINGS, INC., ET AL.

CV 21 943002

Judge: RICHARD A. BELL

Pages Filed: 31

IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY

FRANK MAKOSKI
11139 Caves Rd.
Chesterland, Ohio 44026

and

SUSAN MAKOSKI
11139 Caves Rd.
Chesterland, Ohio 44026

Plaintiffs

v.

ZIMMER HOLDINGS, INC., a/k/a
ZIMMER BIOMET HOLDINGS, INC.
345 East Main Street
Warsaw, Indiana 46580-2746

and

ZIMMER, INC.
1800 West Center Street
Warsaw, Indiana 46581-0708

and

ZIMMER US, INC.
a/k/a ZIMMER
BIOMET US
1800 West Center Street
Warsaw, Indiana 46581-0708

and

ZIMMER OHIO
c/o Zimmer US, Inc.
345 East Main Street
Warsaw, Indiana, 46580-0708

and

CASE NO.:

JUDGE:

COMPLAINT

(JURY DEMAND ENDORSED HEREON)

Electronically Filed 01/15/2021 14:12 / / CV 21 943002 / Confirmation Nbr. 2157986 / CLCKD

S.L. KLABUNDE CORPORATION
6816 Lauffer Road
Columbus, Ohio 43231

and

SCOTT L. KLABUNDE
13751 Luna Drive
Naples, FL 34109

and

RAY HINCH
265 Grey Fox Run
Chagrin Falls, Ohio 44022

and

JOHN DOE and/or JOHN DOE, Inc., 1-10
The true name and/or capacities and addresses of John Doe and/or John Doe, Inc., 1-10 are unknown to Plaintiff. They are individuals and/or business entities that aided and/or participated in the distribution and selling of the Zimmer Hip System medical devices that were implanted into Plaintiff, Frank Makoski.

Defendants

COMPLAINT

Plaintiffs, Frank and Susan Makoski, by and through their counsel, hereby bring this action against Zimmer, Inc., an Indiana Corporation and Zimmer Holdings, Inc. n/k/a Zimmer Biomet Holdings, Inc., an Indiana Corporation, (collectively, referred to as "Zimmer"); Zimmer Ohio, an Ohio Corporation; S. L. Klabunde Corporation, Scott L. Klabunde, Ray Hinch, and

John Doe and/or John Doe, Inc., 1-10, individuals and/or companies (hereafter collectively "Distributors"); allege and state as follows:

NATURE OF THE ACTION

1. This is an action under Ohio Products Liability Act, R.C. 2307.71 et seq., the Ohio Consumer Sales Practices Act ("CSPA") R.C. 1345.02 et seq., breach of express and implied warranties, loss of consortium and punitive damages, brought by Plaintiffs, Frank and Susan Makoski (hereinafter, collectively "Plaintiffs") for injuries arising out of the Zimmer Versys Hip System (Taper Femoral Head with Beaded Fullcoat Stem), hereinafter ("Zimmer Hip System").

2. Defendant Zimmer manufactured and supplied to doctors the Zimmer Hip System, which was implanted in Plaintiff, Frank Makoski on September 20, 2010.

3. The Zimmer Hip System implanted in plaintiff created an unreasonable risk of harm to Plaintiff.

4. The unreasonable risk of pain, swelling, metallosis, adverse local tissue reaction, and/or the need for early revision surgical intervention, whether from corrosion, micromotion, fretting or some other mechanism, renders the Zimmer Hip System a defective product.

5. The selection and implantation of the Zimmer Hip System by Plaintiff's surgeon, Frank J. Meyers, D.O., was a result of the misinformation, marketing, sales, promotion and direction by Zimmer and/or its distributors.

JURISDICTION, VENUE & PARTIES

6. This is a lawsuit over defective hip implant components designed, marketed, manufactured, promoted and sold by Defendants Zimmer, Inc. and Zimmer Holdings, Inc.

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n/k/a Ziimmer Biomet Holdings, Inc. (hereafter collectively "Zimmer") and distributed within Ohio by Defendants Zimmer Ohio, S.L. Klabunde Corporation, Scott Klabunde, Ray Hinch, and John Doe and/or Jon Doe, Inc., 1 through 10 (hereafter collectively "Distributors"); Zimmer and Distributors hereafter collectively referred to as "Defendants".

7. Plaintiff, Frank Makoski and his wife, Plaintiff Susan Makoski, are and were at all times relevant hereto, citizens and residents of the State of Ohio. Plaintiff underwent left hip replacement surgery on September 20, 2010. At that time, the Zimmer Hip System, manufactured, designed, distributed, and warranted by Defendants was implanted into Plaintiff. Plaintiff's surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hip replacement surgery.

8. Zimmer, Inc. is and was at all times relevant, a foreign corporation, organized under the laws of Delaware with principal place of business located in Warsaw, Indiana.

9. Zimmer Holdings, Inc. n/k/a Zimmer Biomet Holdings, Inc. is a foreign corporation organized under the laws of Delaware, with its principal place of business located in Warsaw, Indiana. Zimmer, Inc. is a subsidiary of Zimmer Holdings, Inc. Zimmer distributes their products throughout the United States and internationally.

10. Zimmer, Inc. and Zimmer Holdings, Inc. n/k/a Zimmer Biomet Holdings, Inc. are hereinafter collectively referred to as "Zimmer". Zimmer includes and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents and representatives and any and all other persons

acting on behalf of Defendant Zimmer, Inc. and Defendant Zimmer Holdings, Inc. n/k/a Zimmer Biomet Holdings, Inc.

11. Zimmer Ohio is a distributor of orthopedics for Zimmer, Inc. Upon information and belief, Zimmer Ohio provides Zimmer products and services throughout Ohio.

12. At the time the medical device was implanted in Plaintiff, Frank Makoski, Zimmer Ohio was a Fictitious name recorded with Ohio, entity number 2005871 and was owned and operated by Defendant S.L. Klabunde Corporation.

13. Zimmer Ohio, with entity number 2005871, ceased operations on March 24, 2016 but is still liable for its actions prior to ceasing operations in accordance with R.C. 1701.88.

14. S.L. Klabunde Corporation was an Ohio Corporation with entity number 971524. It ceased operations on November 9, 2017 but is still liable for its actions prior to ceasing operations in accordance with R.C. 1701.88.

15. Scott Klabunde, at the time the medical device was implanted in Plaintiff Frank Makoski, was an officer of the S.L. Klabunde Corporation.

16. Ray Hinch, at the time the medical device was implanted in Plaintiff Frank Makoski, was an officer of the S.L. Klabunde Corporation.

17. Ray Hinch resides in Cuyahoga County.

18. Plaintiffs are informed and believe, and, based upon such information and belief, allege that Defendants John Doe and/or John Doe, Inc., 1 through 10, are individuals and residents of the State of Ohio. The true name and/or capacities and addresses of John Doe and/or John Doe, Inc., 1-10, are unknown to Plaintiff. They are individuals and/or business entities that aided and/or participated in the distribution and selling of the Zimmer Hip System medical devices that were implanted into Plaintiff, Frank Makoski.

Plaintiff will seek leave of Court to amend this Complaint when the name(s) of John Doe and/or John Doe., Inc., 1 through 10, Defendant(s) are ascertained.

19. Zimmer Ohio, S.L. Klabunde, Ray Hinch, Scott Klabunde, and John Doe and/or Jon Doe, Inc., 1 through 10 are hereinafter collectively referred to as "Distributor Defendants".

20. Upon information and belief, at the time the medical device was implanted in Plaintiff, Frank Makoski, Distributor Defendants' relationship with Zimmer was defined in a confidential distributorship agreement.

21. Plaintiffs are under the reasonable belief that Distributor Defendants were involved extensively in the product's promotion, distribution, supply and sale throughout Ohio and specifically related to the devices ultimately implanted in Plaintiff.

22. Upon information and belief, and at all times material hereto, these sales representatives were individually employed, contracted, associated or otherwise engaged as sales persons, detailers and/or representatives of Defendant, Zimmer and/or Distributors Defendants, in furtherance of marketing, promoting, selling and/or distributing the subject medical device. As set forth more completely herein, Distributor Defendants owed various duties to Plaintiff, but breached those duties by committing positive tortious actions against Plaintiff. Those positive tortious acts by the Distributor Defendants, were committed in their individual and/or corporate capacity, and include, but are not limited to, the following:

a. Distributor Defendants failed to convey adequate warnings to Plaintiff. Frank Makoski directly or through Plaintiff's physicians;

b. Distributor Defendants were in the business of marketing, promoting, selling and/or distributing the unreasonably dangerous medical devices which have caused harm to Plaintiff, Frank Makoski;

c. Distributor Defendants negligently distributed, marketed, advertised and/or promoted the dangerous medical devices;

d. Distributor Defendants made negligent misrepresentations regarding the safety and efficacy of the dangerous medical devices;

e. Distributor Defendants negligently failed to provide sufficient information and instructions to Plaintiff Frank Makoski and/or Plaintiff's prescribing physicians regarding the subject medical device including defects therein.

23. All Defendants were also involved in the business of monitoring and reporting adverse events concerning the Zimmer Hip System and having a role in the decision process and response of defendants, if any, related to these adverse events.

24. The Defendants are subject to jurisdiction within the State of Ohio and this Court because:

a. The Defendants are engaged in substantial and not isolated business activity within the State of Ohio, Cuyahoga County;

b. The Defendants' products, including the subject Zimmer Hip System, which they designed and manufactured, were placed into the stream of commerce by the Defendants and were used within the State of Ohio in the ordinary course of commerce, trade or use;

c. The subject Zimmer Hip System caused injury to persons, including Plaintiff, Frank Makoski, within the State of Ohio as a result of the tortious and wrongful

acts and omissions of the Defendants as set forth more fully herein;

d. The Defendants maintain an office or agency within the State of Ohio.

e. Defendant S.L. Klabunde Corporation was a duly organized corporation in the state of Ohio with Ohio, business entity number 971524; and

f. Defendant Ray Hinch, an officer for Defendant Zimmer Ohio and/or Defendant S.L. Klabunde Corporation, is a resident of this county.

25. At all times relevant hereto, the Defendants developed, manufactured, advertised, promoted, marketed, sold and/or distributed the defective Zimmer Hip System, throughout the United States, including within the State of Ohio and specifically including to Plaintiff Frank Makoski's implanting and explanting physicians or practice group, or to the hospital where the Zimmer Hip System was implanted/explanted.

26. The Defendants acted jointly and severally.

27. Plaintiff has reviewed his potential legal claims and causes of actions against Defendants and has chosen to pursue only state law claims, to wit: Ohio Products Liability Act, R.C. 2307.71 et seq. and the Ohio Consumer Sales Practices Act ("CSPA") R.C. 1345.02 et seq. Any reference to federal agency, regulation or rule is stated solely as standard of care or background information and does not raise a federal question.

28. Zimmer knowingly markets to and derives income from patients in Ohio from the sale of the Zimmer Hip System.

29. The liability of Zimmer is so intertwined with that of Zimmer Ohio and S.L Klabunde, that no claims arising from this case can be severed or removed.

30. Subject matter is proper in this Court.

31. Jurisdiction is proper in this Court.

32. Venue is proper in this Court.

33. This is an action for damages in excess of Twenty-Five Thousand Dollars ($25,000.00), exclusive of interest and costs.

ZIMMER HIP IMPLANT SYSTEM DEVICE HISTORY

34. Zimmer, Inc. and Zimmer Holdings, Inc. n/k/a Zimmer Biomet Holdings, Inc., were the designers, manufacturers, and suppliers of the Zimmer Hip System and related components in the business of putting medical devices, including the Plaintiff's hip system on the market. Distributor Defendants were engaged in the business of marketing, distributing, and/or selling the Zimmer Hip System at all times relevant hereto.

35. Zimmer warranted the Zimmer Hip System and placed the device into the United States stream of commerce.

36. Before it set out to design the dual-modular Zimmer Hip System in 2002, Zimmer knew of the danger to human beings if cobalt - chromium metal debris from its products was released into the body through corrosion, micromotion, and/or fretting.

37. Before placing the Zimmer Hip System on the market, Zimmer was required to mitigate risks of the product, including any element of the design that created toxic levels of corrosion and debris that could result in pain, swelling, pseudotumor formation, osteolysis, instability, dislocation, metallosis, trunnionosis, adverse tissue reaction and/or the need for early surgical revision in patients-consumers.

FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED WITH THE ZIMMER HIP IMPLANT SYSTEM

38. Zimmer marketed its hip implants, including the Zimmer Hip System to orthopedic surgeons and hospitals rather than end - user patients.

39. Zimmer had the ability to inform surgeons or hospitals of developing problems or defects in its devices through e-mail, letter, recalls, warnings in product inserts and/or through its product representative(s), who works directly with the surgeon.

40. The mechanical environment of the dual modular junctions place the Zimmer Hip System at increased risk for failure from pain, swelling, pseudotumor formation, metallosis, adverse local tissue reaction, synovitis, osteolysis, and/or dislocation, resulting from excessive wear debris, fretting corrosion and recurrent repassivation.

41. The fretting process (mechanical micromotion) is strongly influenced by distribution of pressure and force at the modular junctions, rendering these junctions vulnerable to accelerated generation of metal wear debris and corrosion.

42. Zimmer did not inform or warn and is still not informing or warning physicians or consumers either through its sales representatives, correspondence, advertising or package inserts of the hazards and defects associated with the Zimmer Hip System.

43. Zimmer never performed any clinical trials and/or studies prior to marketing the Zimmer Hip System.

44. Reassurances of device safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from Zimmer's physician/technical consultants, and/or through industry targeted promotional materials.

45. Defendants were aware of the problems of elevated cobalt at the time that they designed, manufactured, marketed, distributed, and/or sold the Zimmer Hip System. Nonetheless, Defendants continued to market and sell the Zimmer Hip System in reckless disregard for the safety of patients, including Plaintiff.

46. Moreover, despite direct knowledge of significant adverse events reported by patients and physicians, as well as awareness of failures that have been reported in the literature and published in national Registries, Defendants have continued to market the Zimmer Hip System as being safe and effective.

47. From the time that Defendants first began selling the Zimmer Hip System in the United States through today, its product labeling and product information failed to contain adequate information, instructions, and warnings concerning implantation of the product and its increased risks of cobalt poisoning.

PLAINTIFF'S USE OF THE PRODUCTS

48. A defectively designed, manufactured and marketed Zimmer Hip System left the hands of Defendants in its defective condition, delivered into the stream of commerce, and was implanted in Plaintiff, Frank Makoski's left hip on September 20, 2010 by Frank J. Meyers, D.O. Plaintiff was implanted with the components as set forth on the Lake Health Physician's Progress Note, a copy of which is incorporated herein and is attached hereto as Exhibit "A."

49. As a direct and proximate result of Defendants' defective design, manufacture, marketing, distribution, and/or sale of the Zimmer Hip System and placing the defective Device into the stream of commerce, Plaintiff has been injured and damaged as follows:

a. After the implantation of the Zimmer Hip System Device, Plaintiff initially did well, but developed significant pain and instability.

b. Prior to Plaintiff's left hip revision surgery, in January 2019, laboratory studies were conducted which demonstrated, on January 15, 2019, that Plaintiff's cobalt level was elevated. Plaintiff did not learn of this laboratory result until a subsequent doctor's visit, believed to be in February 2019. Plaintiff's symptoms were significantly impacting his activities of daily living.

c. On September 23, 2019, Plaintiff underwent a revision/replacement left hip surgery performed by Matthew Kraay, M.D. due to a failure of the previous left hip arthroplasty and elevated cobalt levels in Plaintiff's blood.

50. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings, of the defective Zimmer Hip System, Plaintiff has suffered and continues to suffer both injuries and damages, including, but not limited to: past, present and future physical and mental pain and suffering; physical disability, and past, present and future, medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

DISTRIBUTORS

51. Zimmer utilized sales representatives, including Distributors, who were responsible for educating Plaintiff's orthopaedic surgeons regarding the claimed advantages of the products at issue in this Complaint, answering any questions Plaintiff's surgeons asked regarding the products, assisting Plaintiff's orthopaedic surgeons at surgery regarding the products, and selling the products to Plaintiff through Plaintiff's orthopaedic surgeon.

52. Distributors or their sales representative(s) were regularly present within the operating room during implantation of the devices sold by Distributors.

53. Distributors received education and training on the surgical techniques, scientific studies, and purported benefits related to the products they sold in their territory.

54. Distributors trained and educated their sales representatives regarding the products at issue, including orthopaedic and surgical training, product design rationale, surgical technique tips, training in the use of implantation tools, training in the selection of hip replacement components to mate with the products at issue, and training on how to sell to orthopaedic surgeons, including training on the alleged advantages of the product at issue over its competitors.

55. Zimmer provided instructional materials to Distributors, including videos of surgeries and exemplar surgical instruments, in an effort to train Distributors (and sales representatives of Distributors) on proper surgical techniques regarding the products at issue in this Complaint.

56. Zimmer insisted that Distributors and their sales representatives take time to review surgical instructions, Instructions for Use ("IFU") and practice with surgical instruments before attending surgeries.

57. Distributors, assisted by Zimmer, organized educational courses where a select surgeon would be paid by either Distributors or by Zimmer to promote the products at issue and discuss surgical technique with surgeons in Distributors' territory.

58. Distributors, assisted by Zimmer, took part in conferences, either in-person, by telephone, or web-case with Zimmer in order to receive product information.

59. Prior to Plaintiff's left hip arthroplasty and ultimately, left hip revision, Distributors provided information to Plaintiff's orthopaedic surgeon, including but not limited to, the advantages of the products at issue compared to competitors' products; information regarding the design rationale for the products at issue; surgical techniques and use of instrumentation during the implantation of the products at issue.

60. The above information was provided to Plaintiff's orthopaedic surgeon with the intended purpose of convincing and inducing Plaintiff's surgeon to use the products at issue instead of other hip implants available for implantation in Plaintiff.

61. At all times relevant to this Complaint, Plaintiff's orthopaedic surgeons, nurses and hospital staff relied on the information and assistance from Distributors and their sales representative agents.

62. Distributors selected and provided the specific Zimmer Hip System components manufactured by Zimmer for use in Plaintiff's surgery and delivered them to the operating room.

63. Upon information and belief, an agent or employee of Distributors, Does 1 through 10, was present in the operating room during Plaintiff's implant surgery.

CAUSES OF ACTION

COUNT I
DEFECTIVE DESIGN - O.R.C. 2307.75
(AGAINST ALL DEFENDANTS)

64. Plaintiff incorporates by reference paragraphs 1 through 63 of this Complaint, as if fully set forth herein and further alleges as follows:

65. The Zimmer Defendants had a duty to design and manufacture, and all Defendants had a duty to place into the stream of commerce, distribute, market, promote and sell, the

Zimmer Hip System so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

66. On and prior to January 2010, the Zimmer Defendants were engaged in the business of designing, manufacturing, marketing, distributing and selling orthopedic hip implants and did design, manufacture, distribute, market and sell the Zimmer Hip System, and Distributor defendants (including individual Defendants John Doe and/or John Doe, Inc. 1-10) were engaged in the business of marketing, distributing and selling orthopaedic hip implants and did distribute, market and sell the Zimmer Hip Implant System.

67. The Zimmer Defendants did in fact design and manufacture, while all Defendants were engaged in selling, distributing, supplying and/or promoting the Zimmer Hip System to Plaintiff Frank Makoski and Plaintiff's implanting physician.

68. Defendants expected the Zimmer Hip System they were selling, distributing, supplying, manufacturing and/or promoting to reach, and it did in fact reach, implanting physicians and consumers in the State of Ohio. including Plaintiff Frank Makoski and Plaintiff's implanting physician, without substantial change in the condition.

69. Plaintiff is in the class of persons that Defendants should reasonably foresee as being subject to the harm caused by the defectively designed Zimmer Hip System, insofar as Plaintiff was the type of person for whom the hip implants were intended to be used.

70. At the time the Zimmer Hip System left the Defendants' possession and the time the Zimmer Hip System entered the stream of commerce in the State of Ohio, it was in an unreasonably dangerous or defective condition. These defects include, but are not limited to, the following:

a. the Zimmer Hip System was not reasonably safe as intended to be used;

b. the Zimmer Hip System had an inadequate design for the purpose of hip replacement;

c. the Zimmer Hip System contained unreasonably dangerous design defects, including the ability to result in increased cobalt in the Hip Implant System recipient's bloodstream.

d. the Zimmer Hip System's unstable and defective modular design resulted in a hip prosthesis which had risks which exceeded the benefits of the medical device;

e. the Zimmer Hip System was not appropriately or adequately tested before its distribution; and

f. the Zimmer Hip System had an unreasonably high propensity for causing elevated blood cobalt levels despite normal and expected use of the Zimmer Hip System.

71. At the time of the Zimmer Defendants' initial design and manufacture, and of all Defendants' marketing and sale of the Zimmer Hip System, a feasible, alternative safer design for the Zimmer Hip System was known and available.

72. At the time of and subsequent to the Zimmer Defendants' initial design and manufacture and all Defendants' marketing and sale of the Zimmer Hip System, including prior to the time of Plaintiff Frank Makoski's left hip implant surgery, Defendants had the ability to eliminate the unsafe character of the Zimmer Hip System without impairing its usefulness.

73. Had the Zimmer Defendants properly and adequately tested the Zimmer Hip System, they would have discovered the defective nature of the product.

74. The Zimmer Hip System, manufactured and supplied by the Zimmer Defendants and distributed, marketed, promoted and sold by all Defendants, was, therefore, defective in

design or formulation in that, when it left the hands of Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

75. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the Zimmer Hip System for its intended or reasonably foreseeable purpose, and pursuant to instruction, guidance, education and training specifically provided by Defendants.

76. At all times relevant hereto, the Zimmer Hip System was dangerous, unsafe and defective in design including but not limited to its tendency to: (a) create dangerous and harmful cobalt levels in the patient's body; (b) cause pain; (c) inhibit mobility; and (d) require revision surgery with predictable cascading complications.

77. Defendants knew or should have known of the unreasonably dangerous and serious risks associated with the design of the Zimmer Hip System.

78. Such risks were scientifically known and/or knowable to Defendants.

79. Defendants knew or should have known of the product's dangers.

80. Defendants either performed inadequate evaluation and testing; kept themselves willfully blind to the dangers; hid the dangers from physicians and patients, or some combination of the three.

81. As a direct, legal, and proximate result of Defendants' dangerous design, Plaintiff sustained injuries as set forth above.

82. Defendants' dangerous design and failure to adequately test contributed to cause the injuries suffered by Plaintiff.

83. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Zimmer Hip System, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT II
FAILURE TO WARN - O.R.C. 2307.76
(AGAINST ALL DEFENDANTS)

84. Plaintiff incorporates by reference paragraphs 1 through 83 of this Complaint, as if fully set forth herein and further alleges as follows:

85. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer Hip System, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, including the Plaintiff, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer Hip System.

86. Defendants distributed and sold the Zimmer Hip System in its original form of manufacture, which included the defects described herein.

87. The Zimmer Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it contained an absence of warnings or limitations on when such device should be selected over safer alternatives.

88. The Zimmer Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it contained an absence of warnings alerting the medical community and patients as to the dangerous risks associated with the Zimmer Hip System when used for its intended and reasonably foreseeable purpose.

89. The risks associated with the Zimmer Hip System when used for its intended and reasonably foreseeable purpose, include but are not limited to: (a) the creation of dangerous and harmful metal debris in the patient's body; (b) pain; (c) mobility inhibition; and (d) likelihood of revision surgery with predictable cascading complications.

90. The Zimmer Hip System was expected to and did reach Plaintiff Frank Makoski and Plaintiff's implanting physician, in the State of Ohio without substantial change or adjustment in its condition as manufactured and sold by Defendants.

91. The Zimmer Hip System devices designed, developed, tested, manufactured, distributed, promoted, marketed and/or sold or otherwise placed into the stream of commerce by Defendants were in a dangerous and defective condition and posed a threat to any user or consumer of the Zimmer Hip System devices.

92. At all times relevant hereto, Plaintiff was a person the Defendants should have considered to be subject to the harm caused by the defective nature of the Zimmer Hip System devices.

93. Defendants' Zimmer Hip System was implanted in Plaintiff and used in the manner for which it was intended.

94. This use has resulted in physical, financial, emotional and other injuries to Plaintiff.

95. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and Plaintiff's prescribing physician, of the true risks of the Zimmer Hip System, including that the Zimmer Hip System was susceptible to generating significant and toxic amounts of cobalt in patients, causing severe pain and injury, and requiring further treatment, including revision surgery and/or hip replacement.

96. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer Hip System. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the Zimmer Hip System, or no consumer, including Plaintiff, would have purchased and/or used the Zimmer Hip System.

97. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer Hip System.

98. The Zimmer Hip System, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer Hip System dual modular components and the development of corrosion, metal fatigue, failure, micromotion and/or release of significant amounts of metal debris and/or ions, causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Zimmer Hip System.

99. The Zimmer Hip System, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Zimmer Hip System resulting in revision surgery while knowing that a safer alternative design existed.

100. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

101. Plaintiff and Plaintiff's physician, used the Zimmer Hip System for its intended purpose, i.e., hip replacement.

102. Plaintiff could not have discovered any defect in the Zimmer Hip System through the exercise of due care.

103. Defendants, as designers, manufacturers, distributors, promoters, marketers and/ or sellers of medical devices are held to the level of knowledge of experts in their field.

104. Neither Plaintiff nor Plaintiff's implanting and/or explanting physician had substantially the same knowledge about the Zimmer Hip System as Defendants.

105. Defendants reasonably should have known the Device was unsuited for active individuals such as Plaintiff Frank Makoski.

106. The warnings and instructions provided with the Zimmer Hip System and through Defendants did not adequately educate and train medical providers as to the risk of side effects, or the cost-benefit analysis necessary for justified use of this product versus safer alternative designs.

107. Defendants had a continuing duty to warn the medical community and public, including Plaintiff and Plaintiff's healthcare providers, of the potential risks and increased failure rates or propensity for failure associated with the Zimmer Hip System.

108. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff has sustained and will continue to sustain severe physical injuries, severe mental anguish, economic losses and other damages, as set forth herein.

109. As a direct result of Defendants' failure to warn and/or inadequate warning and their other tortious conduct, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

110. As a direct and proximate result of Defendants' failure to warn and/or inadequate warning and their other tortious conduct, as set forth herein, Plaintiff has suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

COUNT III
MANUFACTURING DEFECT - O.R.C. 2307.04
(AGAINST ZIMMER DEFENDANTS)

111. Plaintiff incorporates by reference paragraphs 1 through 110 of this Complaint, as if fully set forth herein and further alleges as follows:

112. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the Zimmer Hip System, in a condition which

rendered it unreasonably dangerous due to its propensity to result in early failure of the device. The subject product was unreasonably dangerous in construction or composition.

113. The Zimmer Hip System manufactured and/or supplied by Defendants was defective in manufacture, construction or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that the Zimmer Hip System could fail early in patients and cause cobalt poisoning, therefore giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgery, Defendants continued to market the Zimmer Hip System as a safe and effective hip replacement system.

114. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant, Plaintiff suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

COUNT IV
BREACH OF EXPRESS WARRANTY
(AGAINST ZIMMER DEFENDANTS)

115. Plaintiff incorporates by reference paragraphs 1 through 114 of this Complaint, as if fully set forth herein and further alleges as follows:

116. Defendants advertised, labeled, marketed and promoted the Zimmer Hip System, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the

Zimmer Hip System would conform to the representations. More specifically, Defendants represented that the Zimmer Hip System was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff's condition.

117. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

118. The Zimmer Hip System did not conform to the representations made by Defendants in that the Zimmer Hip System was not safe and effective, was not safe and effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat in individuals, such as Plaintiff.

119. At all relevant times, Plaintiff used the Zimmer Hip System for the purpose and in the manner intended by Defendants.

120. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

121. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

122. Zimmer breached the express warranty it provided with the device.

123. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of the Zimmer Hip System, Plaintiff was implanted with the Zimmer Hip System and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, instability

and loss of balance, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT V
BREACH OF IMPLIED WARRANTY
(AGAINST ZIMMER DEFENDANTS)

124. Plaintiff incorporates by reference paragraphs 1 through 123 of this Complaint, as if fully set forth herein and further alleges as follows:

125. The Zimmer Hip System was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Zimmer Hip System minimally safe for its expected purpose.

126. At all relevant times, Plaintiff used the Zimmer Hip System for the purpose and in the manner intended by Defendants.

127. Plaintiff and Plaintiff's physicians, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

128. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

129. Zimmer impliedly warranted that the Zimmer Hip System and its component parts were merchantable and fit for the ordinary and intended purposes for which hip systems are used.

130. Plaintiff was a foreseeable user of the Zimmer Hip System.

131. Plaintiff's surgeon, as purchasing agent, purchased the Zimmer Hip System for Plaintiff from Zimmer.

132. At all times relevant to this Complaint, Plaintiff was and is in privity with Zimmer.

133. Plaintiff used the product for its ordinary and intended purpose.

134. The Zimmer Hip System failed while being used for its ordinary and intended purpose.

135. As a direct and proximate result of Zimmer's breach of implied warranty of merchantability, Plaintiff suffered injuries as described specifically above.

COUNT VI
OHIO CONSUMER SALES PRACTICE ACT - O.R.C. 1345 et seq
(AGAINST ALL DEFENDANTS)

136. Plaintiff incorporates by reference paragraphs 1 through 135 of this Complaint, as if fully set forth herein and further alleges as follows:

137. Defendants are the researchers, developers, manufacturers, distributors, marketers, promoters, suppliers and sellers of the Zimmer Hip System, which they represented would be free from defects and fit for its intended purpose.

138. Defendants advertised, labeled, marketed and promoted its product, Zimmer Hip System, representing the quality to health care professionals, the FDA, Plaintiff, Plaintiff's surgeon, and the public in such a way as to induce its purchase or use. More specifically, Defendants represented that the Zimmer Hip System was safe and effective for use by individuals such as Plaintiff or that it was safe and effective to treat Plaintiff's condition.

139. Defendants knew or should have known that the Zimmer Hip System did not or would not conform to Defendants' representations and promises.

140. Defendants' concealed knowledge of the serious risks associated with the Zimmer Hip System and concealed testing and research data, or selectively and misleadingly revealed or analyzed testing and research data.

141. Defendants' actions and conduct, as alleged in this Complaint, constitute deceptive trade practices in the course of Defendants' business in violation of the provisions of Ohio Revised Code §1345 et seq.

142. As a direct and proximate result of Defendants' unfair and/or deceptive conduct, in or affecting commerce, Plaintiff is entitled to recover treble damages and attorney's fees from Defendants, pursuant to the provisions of Ohio Revised Code §1345 et seq.

COUNT VII
PUNITIVE DAMAGES - O.R.C 2307.80
(AGAINST ALL DEFENDANTS)

143. Plaintiff incorporates by reference paragraphs 1 through 142 of this Complaint, as if fully set forth herein and further alleges as follows:

144. Defendants knew or should have known that the Zimmer Hip System it designed, manufactured, distributed and sold either directly or indirectly to Plaintiff Frank Makoski was defective and posed an unreasonable risk of harm to Plaintiff Frank Makoski; despite having knowledge of this danger, Defendants concealed this information from the public including Plaintiff Frank Makoski.

145. Defendants' misconduct as described in this Complaint, for which Plaintiffs are entitled to recover compensatory damages, manifested a flagrant disregard of the safety of those persons who might foreseeably have been harmed by the Zimmer Hip System, including Plaintiff Frank Makoski, which justifies the imposition of punitive damages under O.R.C. 2307.80.

COUNT VIII
LOSS OF CONSORTIUM
(AGAINST ALL DEFENDANTS)

146. Plaintiff Susan Makoski incorporates by reference paragraphs 1 through 145 of this Complaint, as if fully set forth herein and further alleges as follows:

147. Plaintiff Susan Makoski was and is the lawful spouse of Plaintiff Frank Makoski and in such capacity, was and is entitled to the comfort, enjoyment, society and services of her spouse.

148. As a direct and proximate result of the foregoing allegations, Plaintiff Susan Makoski was deprived of the comfort, enjoyment, society and services of her spouse, has suffered and will continue to suffer economic loss, and otherwise has been emotionally and economically injured. Plaintiff Susan Makoski's injuries and damages are permanent and will continue into the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment and an award of damages against Defendants, jointly and severally, as follows:

(a) for Frank Makoski's special damages, to include past and future medical and incidental expenses, according to proof;

(b) for Frank Makoski's past and future loss of earnings and/or earning capacity, according to proof;

(c) for Frank Makoski's past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;

(d) for Plaintiff Susan Makoski's damages for loss of services, consortium, and economic loss;

(e) for pre-judgment and post-judgment interest;

(f) for the costs of this action;

(f) attorney fees; and

(g) granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

/s/ Richard L. Demsey
Richard L. Demsey, Esquire
S. Ct. No. 0003518
Justin D. Gould, Esquire
S. Ct. No. 0082653

RICHARD L. DEMSEY CO., L.P.A.
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1350 Euclid Avenue, Suite 1550
Cleveland, Ohio 44115
Tel: 216-263-7900; Fax: 216-263-7901
Email: rdemsey@demseylaw.com
Email: jgould@demseylaw.com

Attorneys for Plaintiffs

JURY DEMAND ENDORSED HEREON

A trial by jury by the maximum number of jurors permitted by law is hereby demanded.

/s/ Richard L. Demsey
Richard L. Demsey, Esquire
S. Ct. No. 0003518
Justin D. Gould, Esquire
S. Ct. No. 0082653

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Attorneys for Plaintiffs

LAKE HEALTH
PHYSICIAN PROGRESS NOTES

Pt.: MAKOSKI, FRANK A
Acct: 1024201196 Unit#: 217454
BD: 06/08/50 60Y Sex M
Dr. MYERS, FRANK J
Adm Date: WPO

DATE	Notes Must be SIGNED and DATED by the Physician

9-2010 left hip

LOT 61428548 EDI: 00820005222 REF 6200-52-22
TRILOGY® ACETABULAR SYSTEM
SHELL WITH CLUSTER HOLES
POROUS 52 MM O.D.
+H1240052000852221/2008161428548D10H
2020-03
zimmer

LOT 61504853 EDI:00825006530 REF 8250-65-30
BONE SCREW SELF-TAPPING
6.5 MM DIA. 30 MM LENGTH
+H1240082500653301/2012161504853D10D
2020-04
zimmer

LOT 61542839 EDI: 00801803203 REF 8018-32-03
VERSYS® HIP SYSTEM
FEMORAL HEAD 12/14 TAPER
32 MM DIA. +3.5 MM NECK LENGTH
+H1240080180320312018261542839F10Q
2020-06
zimmer

LOT 61540444 EDI: 00631005032 REF 6310-50-32
TRILOGY® ACETABULAR SYSTEM
LINER 10 DEGREE ELEVATED RIM
LONGEVITY® CROSSLINKED POLYETHYLENE
32 MM I.D. FOR USE WITH 50/52/54 MM O.D. SHELL
+H1240063100503211/1524381540444H10F
2015-08
zimmer

LOT 61563807 EDI: 00625006525 REF 6250-65-25
BONE SCREW SELF-TAPPING
6.5 MM DIA. 25 MM LENGTH
+H1240062500652511/2021361563807G10Q
2020-07
zimmer

LOT 61023579 EDI: 00784301356 REF 7843-13-56
VERSYS® HIP SYSTEM
FEMORAL STEM BEADED FULLCOAT COLLARED
12/14 NECK TAPER EXTENDED NECK OFFSET
SIZE 13 LM BODY
+H1240078430135611/1830481023579J084
2018-10
zimmer

BYLAWS, RULES AND REGULATIONS STATE: "IT IS THE RESPONSIBILITY OF THE ATTENDING PHYSICIAN TO ENSURE THAT A PROGRESS NOTE IS WRITTEN DAILY."

PN4719
1204-4719

[redacted]

PLAINTIFF'S EXHIBIT A